510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k052525

B. Purpose for Submission:

Clearance to market CYBOW 11 Series Reagent Strips for Urinalysis

C. Measurand:

Urobilinogen, bilirubin and its conjugates, ketones (acetoacetic acid), blood, glucose, protein, nitrite, leukocytes, glucose, specific gravity, pH, and ascorbic acid in urine.

D. Type of Test:

Qualitative and semi-quantitative urine tests

E. Applicant:

DFI Co., Ltd.

F. Proprietary and Established Names:

CYBOW 11 Series Reagent Strips for Urinalysis

G. Regulatory Information:

1. Regulation section:
   21 CFR §864.6550: Occult blood test.
   21 CFR §862.1340: Urinary glucose (nonquantitative) test system.
   21 CFR §862.1785: Urinary urobilinogen (nonquantitative) test system.
   21 CFR §862.1115: Urinary bilirubin and its conjugates (nonquantitative) test system.
   21 CFR §862.1435: Ketones (nonquantitative) test system.
   21 CFR §862.1645: Urinary protein or albumin (nonquantitative) test system.
   21 CFR §862.1510: Nitrite (nonquantitative) test system.
   21 CFR §864.7675: Leukocyte peroxidase test.
   21 CFR §862.1550: Urinary pH (nonquantitative) test system.
   21 CFR §862.1095: Ascorbic acid test system.

2. Classification:

   Class II

3. Product code:

   Occult blood test - JIO
   Urinary glucose (nonquantitative) test system - JIL
   Urinary urobilinogen (nonquantitative) test system - CDM
   Urinary bilirubin and its conjugates (nonquantitative) test system - JJB
   Ketones (non-quantitative) test system - JIN
   Urinary protein or albumin (non-quantitative) test system - JIR
   Nitrite (non-quantitative) test system - JMT
   Leukocyte peroxidase test - LJX
   Urinary pH (nonquantitative) - CEN
   Ascorbic acid test system - JMA

4. Panel:
   Chemistry (75)
   Hematology (82)

H. Intended Use:

1. Intended use(s):

   CYBOW 11 Reagent Strips are for the rapid visual determination of urobilinogen, glucose, bilirubin, ketones (acetoacetic acid), specific gravity, blood, pH, protein, nitrite, leukocytes and ascorbic acid in urine.

2. Indication(s) for use:

   CYBOW 11 Reagent Strips are for single use in professional near-patient (point of-care) and centralized laboratory locations. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas:
   • Kidney function
   • Urinary tract infections
   • Carbohydrate metabolism (e.g. diabetes mellitus)
   • Liver function
   • Acid-base balance
   • Urine concentration

   The results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed. The test is to be read visually.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Not applicable to this device.

I. Device Description:

CYBOW Reagent Strips are dip-and-read test strips for In Vitro Diagnostic Use only for testing analytes in urine. Test result may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection. It is measured by comparison of test paper attached to a plastic strip to a color chart printed on the vial label.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer Corporation MULTISTIX 10SG Reagent Strips

2. Predicate 510(k) number(s):

   k852611

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Specimen	Urine	Same
Intended Use Audience	Professional use	Same
Test results	Color comparison	Color comparison

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP6-A: "Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach"; Approved Guideline, 2003

CLSI EP09-A2: "Method Comparison and Bias Estimation Using Patient Samples"; Approved Guideline, 2002

CLSI EP12-A: "User Protocol for Evaluation of Qualitative Test Performance"; Approved Guideline, 2002

ISO 2895-1: “Sampling Procedures for Inspection by Attributes - Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection-Second Edition”

L. Test Principle:

The device is composed of multiple chemically reactive spots separate from each other on a plastic strip. Read-out is accomplished by visually matching the position and color of an exposed spot to a color coded chart provided with the device.

For the detection of urobilinogen, the device employs a modified Ehrlich’s reaction. Urobilinogen reacts with Ehrlich’s reagent to form a red-colored compound. Color changes from light orange-pink to dark pink.

For the detection of glucose, the device employs glucose oxidase to catalyze the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the reaction pad by the action of peroxidase.

For the detection of bilirubin, diazonium salts in an acidic matrix on the strip undergo an azo-coupling reaction with bilirubin to form an azodye. The spot color changes from light tan to beige or light pink.

The device uses Legal’s test-nitroprusside reaction for the detection of ketones. Acetoacetic acid in an alkaline medium reacts with nitroferricyanide to produce a color change from beige to purple

The device uses a correlation between the concentration of ionic species and the sample’s specific gravity to report an estimated specific gravity. Ionic solutes present in the urine release protons from a polyelectrolyte. The released protons decrease the pH on that strip spot and produce a color change in bromothymol blue from blue-green to yellow-green.

To detect blood, the device exploits the pseudo-peroxidase activity of the haem moiety of hemoglobin and myoglobin. A chromogen is oxidized by a hydroperoxide in the presence of haem and changes color from yellow to blue

The devices employs a combination of methyl red and bromothymol blue indicators to give distinct color changes from orange to green to blue (pH 5.0 to 9.0).

To qualitatively estimate protein concentration, the device uses the “error of indicators” principle. Proteins interact with an ionizable electrolyte driving the release of protons which in turn interact with a spectator indicator. The color change in the indicator is correlated with the protein concentration.

The device detects nitrite through a reaction of the nitrite with an aromatic amine. The resulting diazo compound reacts with another aromatic to form a pink compound.

One location on the strip contains an indoxyl ester and diazonium salt. Leukocytes contain an esterase that hydrolyzes the indoxyl ester. The liberated compound reacts with the diazonium salt on the strip to generate a purple compound. The concentration of leukocytes is correlated with a color change from beige to violet.

The ascorbic acid test uses the decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from gray-blue to yellow.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run and Within-day precisions were determined at the manufacture's site, using level 1 and level 2 urinalysis controls.

Reproducibility testing was done in accordance with CLSI EP12-A "User Protocol for Evaluation of Qualitative Test Performance". Two clinical pathologists were employed as readers for the precision testing.

For within-run precision testing, twenty replicates were run on each of two levels of liquid urine controls. Each of the twenty replicates was assayed consecutively, using strips obtained from each of 3 lots of vial. For within-day precision testing, two levels were analyzed in duplicate, one a day, for 20 days using strips obtained from 3 lots of vials. Percentage agreements were calculated using the concentrations specified in the control labeling and the concentration ranges specified for the strip.

The results of the within-day testing:

	Negative Control					Positive Control				
Analyte	Expected Result	Lot 10205	Lot 10721	Lot 20108	Total Agreement	Expected Result	Lot 10205	Lot 10721	Lot 20108	Total Agreement
Urobilinogen	Negative	20/20	20/20	59/60	59/60 (98.3%)	4 mg/dl	19/20	19/20	18/20	56/60 (93.3%)
Glucose	Negative	20/20	20/20	20/20	60/60 (100%)	1000 mg/dl	19/20	19/20	20/20	58/60 (96.6%)
Bilirubin	Negative	19/20	20/20	19/20	58/60 (96.7%)	+++	17/20	17/20	18/20	52/60 (86.7%)
Ketones (acetoacetic acid)	Negative	20/20	20/20	20/20	60/60 (100%)	40 mg/dl	20/20	17/20	19/20	56/60 (93.3%)
Specific Gravity	1.020	17/20	18/20	19/20	54/60 (90%)	1.020	17/20	18/20	17/20	52/60 (86.7%)
Blood	Negative	19/20	20/20	20/20	59/60 (98.3%)	250 RBC/ul	19/20	20/20	19/20	58/60 (96.6%)
pH	6	18/20	20/20	19/20	57/60 (95%)	7	17/20	17/20	18/20	52/60 (86.7%)

	Negative Control					Positive Control				
Analyte	Expected Result	Lot 10205	Lot 10721	Lot 20108	Total Agreement	Expected Result	Lot 10205	Lot 10721	Lot 20108	Total Agreement
Protein	Negative	20/20	20/20	19/20	59/60 (98.3%)	100 mg/dl	19/20	20/20	19/20	58/60 (96.7%)
Nitrite	Negative	20/20	19/20	20/20	59/60 (98.3%)	Positive	20/20	20/20	20/20	60/60 (100%)
Leukocytes	Negative	20/20	20/20	20/20	60/60 (100%)	75 WBC/ul	18/20	19/20	17/20	54/60 (90.0%)
Ascorbic	Negative	20/20	20/20	20/20	60/60 (100%)	Negative	20/20	20/20	20/20	60/60 (100%)

The results of the within-run testing:

	Negative Control					Positive Control				
Analyte	Result	Lot 10205	Lot 10721	Lot 20108	Total Agreement	Expected Result	Lot 10205	Lot 10721	Lot 20108	Total Agreement
Urobilinogen	Negative	20/20	20/20	20/20	60/60 (100%)	4 mg/dl	18/20	19/20	18/20	55/60 (91.7%)
Glucose	Negative	20/20	20/20	20/20	60/60 (100%)	1000 mg/dl	19/20	20/20	18/20	57/60 (95%)
Bilirubin	Negative	20/20	20/20	20/20	60/60 (100%)	+++	18/20	17/20	17/20	52/60 (86.7%)
Ketones (acetoacetic acid)	Negative	20/20	20/20	20/20	60/60 (100%)	40mg/dl	19/20	18/20	20/20	57/60 (95%)
Specific Gravity	1.020	18/20	20/20	19/20	57/60 (95%)	1.020	17/20	18/20	17/20	52/60 (86.7%)
Blood	Negative	20/20	20/20	20/20	60/60 (100%)	250 RBC/ul	20/20	20/20	19/20	59/60 (86.7%)
pH	6	19/20	17/20	18/20	54/60 (90%)	7	18/20	19/20	17/20	54/60 (90%)
Protein	Negative	20/20	20/20	19/20	60/60 (100%)	100 mg/dl	20/20	19/20	19/20	58/60 (96.7%)
Nitrite	Negative	20/20	20/20	20/20	60/60 (100%)	Positive	20/20	20/20	20/20	60/60 (100%)
Leukocytes	Negative	20/20	20/20	20/20	60/60 (100%)	75 WBC/ul	17/20	18/20	18/20	53/60 (88.3%)
Ascorbic	Negative	20/20	20/20	20/20	60/60 (100%)	Negative	20/20	20/20	20/20	60/60 (100%)

b. Linearity/assay reportable range:

The company assessed the range of the device by repeated testing with urine containing known concentrations of the measured analytes.

Samples of the candidate device were randomly selected from routine production following ISO 2895-1: "Sampling procedures for inspection by attribute-sampling scheme indexed by acceptances quality limit (AQL) by lot-to-lot inspection". Strips were selected from three manufacturing lots.

Test material was created by spiking analytes into negative urine or by serial dilution with negative urine of a known high concentration of an analyte in urine. Test material was adjusted to match the mid-point of a concentration range for a particular color block on the strip – if a particular color indicated a concentration of 2-4 mg/dL, the test urine was adjusted to 3 mg/dL.

Three pathologists independently read each of the three lots of test strips. Tests were done 10 times at each test concentration with 3 different product lots. Sample application was done according to the device's product insert. Color comparisons were made against the color chart that accompanies the product.

The company illustrated the performance of their device by presenting the results of these tests as a scoring matrix. The results of this testing is summarized below.

For urobilinogen, the company demonstrated:

		Applied Concentration, mg/dL				
		0.1	1	2	4	8
Concentration reported by Strip, mg/dL	8	0	0	0	1	28
	4	0	0	2	25	2
	2	0	1	26	3	0
	1	0	29	2	1	0
	0.1	30	0	0	0	0
Total Number of samples applied at concentration		30	30	30	30	30

For glucose, the company demonstrated:

		Applied Concentration, mg/dL				
		Neg.	100	250	500	1000
Concentration reported by Strip, mg/dL	1000	0	0	0	2	26
	500	0	0	2	27	4
	250	0	1	27	1	0
	100	0	29	1	0	0
	Neg.	30	0	0	0	0
Total Number of samples applied at concentration		30	30	30	30	30

For bilirubin, the company demonstrated:

	Neg.	+	++	+++
+++	0	0	3	29
++	0	4	27	1
+	0	25	0	0
Neg.	30	1	0	0
Total Number of samples applied at concentration	30	30	30	30

For ketones, the company demonstrated:

		Applied Concentration, mg/dL				
		Neg.	5	15	40	100
Concentration reported by Strip, mg/dL	100	0	0	0	2	28
	40	0	0	1	25	2
	15	0	0	28	3	0
	5	0	29	1	0	0
	Neg.	30	1	0	0	0
Total Number of samples applied at concentration		30	30	30	30	30

For the specific gravity, the company demonstrated:

		Applied Specific Gravity						
		1.000	1.005	1.010	1.015	1.020	1.025	1.030
Specific gravity reported by Strip	1.030	0	0	0	0	0	2	29
	1.025	0	0	0	0	4	26	1
	1.020	0	0	0	1	24	2	0
	1.015	0	0	1	26	2	0	0
	1.010	0	2	26	3	0	0	0
	1.005	0	28	3	0	0	0	0
	1.000	30	0	0	0	0	0	0
Total Number of samples applied at concentration		30	30	30	30	30	30	30

For hemolyzed blood, the company demonstrated:

		Applied RBC/ µl			
		Neg.	10 RBC/µl	50 RBC/µl	250 RBC/µl
RBC/µl reported by Strip	250 RBC/µl	0	0	3	30
	50 RBC/µl	0	3	26	0
	10 RBC/µl	0	27	1	0
	Neg.	30	0	0	0
	Total Number of samples applied at concentration	30	30	30	30

For non-hemolyzed blood, the company demonstrated:

		Applied Non-hemolyzed blood		
		Neg.	+	++
Non-hemolyzed blood reported by Strip	++	0	4	27
	+	0	26	3
	Neg.	30	0	0
	Total Number of samples applied at concentration	30	30	30

For pH, the company demonstrated:

		Applied pH					
		5	6	6.5	7	8	9
pH reported by Strip	9	0	0	0	0	1	29
	8	0	0	0	2	28	1
	7	0	0	3	28	1	0
	6.5	0	0	23	0	0	0
	6	1	26	4	0	0	0
	5	29	4	0	0	0	0
	Total Number of samples applied at concentration	30	30	30	30	30	30

For protein, the company demonstrated:

		Applied protein, mg/dL					
		Neg.	15	30	100	300	1000
Protein reported by Strip, mg/dL	1000	0	0	0	0	1	29
	300	0	0	0	2	28	1
	100	0	0	3	28	1	0
	30	0	0	23	0	0	0
	15	1	26	4	0	0	0
	Neg.	29	4	0	0	0	0
Total Number of samples applied at concentration		30	30	30	30	30	30

For nitrite, the company demonstrated:

		Applied nitrite		
		Neg.	Tr.	Pos.
Nitrite reported by Strip	Pos.	0	1	30
	Tr.	1	28	0
	Neg.	29	1	0
Total Number of samples applied at concentration		30	30	30

For leukocytes, the company demonstrated:

		Applied leukocytes/µl			
		Neg.	25 Leu/µl	75 Leu/µl	500 Leu/µl
Lue/µl reported by Strip	500 Leu/µl	0	0	1	29
	75 Leu/µl	0	1	26	1
	25 Leu/µl	0	25	3	0
	Neg.	30	4	0	0
Total Number of samples applied at concentration		30	30	30	30

For ascorbic acid, the company demonstrated:

		Applied ascorbic acid		
		Neg.	20 mg/dL	40 mg/dL
Ascorbic acid reported by Strip	40 mg/dL	0	4	27
	20 mg/dL	0	26	3
	Neg.	30	0	0
Total Number of samples applied at concentration		30	30	30

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The company used a combination of real-time and accelerated aging studies to demonstrate their claimed shelf life. The company used samples taken from three different manufacturing lots in assessing their shelf life.

The company conducted real time aging studies to empirically determine the shelf life of their device. Bottles from each manufacturing lot were stored in an environmental chamber at temperatures ranging from 2-30 ºC. The relative humidity was set to less the 30%. Strips were withdrawn monthly and tested with negative and spiked positive urine samples. The company demonstrated that the performance of their device did not change over the course of this 2 year storage test.

In addition, the company conducted accelerated aging studies at storage temperatures of 40 ºC, 50 ºC, and 60 ºC. Data supplied by company demonstrated that the strips could be stored at 60 ºC for 3 weeks without a change in performance. Strips could be stored at 50 ºC for 4 weeks and 40 ºC for 6 weeks without a change in performance.

The company conducted tests at room temperature and high relative humidity to quantify the impact of ambient water vapor. Strips stored at less that 50% relative humidity did not demonstrate a change in performance over a 2 year period.

The data provided by the company supports their claim that the CYBOW 11 Reagent strips for Urinalysis are stable for 24 months when stored between 15-30 ºC and a relative humidity of less than 50%.

d. Detection limit:

The company demonstrated their detection limit by challenging the concentration cutoff with samples adjusted to concentrations 20% above and 20% below the cutoff concentration specified for the analyte. The company

conducted this study using 20 strips from each of 3 lots for a total of 60 measurements at each concentration.

For urobilinogen, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	58	0	0
Positive	2	60	60
Percent Correct	96.7%	100%	100%
Cutoff Used	2 Ehrlich units/dL		

For glucose, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	57	1	
Positive	3	59	60
Percent Correct	95%	98.3%	100%
Cutoff Used	50 mg/dL		

For bilirubin, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	59	0	0
Positive	1	60	60
Percent Correct	98.3%	100%	100%
Cutoff Used	0.5 mg/dL		

For ketones, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	57	0	0
Positive	3	60	60
Percent Correct	95%	100%	100%
Cutoff Used	5 mg/dL		

For hemolyzed blood, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	52	1	0
Positive	8	59	60
Percent Correct	86.7%	98.3%	100%
Cutoff Used	10 RBC/µL		

For non-hemolyzed blood, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	50	2	0
Positive	10	58	60
Percent Correct	83.3%	96.7%	100%
Cutoff Used	10 RBC/µL		

For protein, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	42	8	0
Positive	18	52	60
Percent Correct	70.0%	86.7%	100%
Cutoff Used	12 mg/dL		

For nitrite, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	55	0	0
Positive	5	60	60
Percent Correct	91.7%	100%	100%
Cutoff Used	0.05 mg/dL		

For leukocytes, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	41	5	0
Positive	19	55	60
Percent Correct	68.3%	91.7%	100%
Cutoff Used	23 WBC/µL		

For ascorbic acid, the company demonstrated:

Sample	0.8*Cutoff Conc.	Cutoff Conc.	1.2*Cutoff Conc.
Normal	58	0	0
Positive	2	60	60
Percent Correct	96.7%	100%	100%
Cutoff Used	20 mg/dL		

e. Analytical specificity:

The company conducted tests using analytes suspected of interfering with their device. Fresh negative urine was spiked with the analyte of interest and the interfering analyte. The company documented the impact of the interfering analyte in their product insert. A summary of the company's findings:

Test	Interfering Analyte	Impact on test
Urobilinogen	p-amino salicylic acid	False positive
	Azo gantrinsin	Test inoperative – unable to read
Glucose	High specific gravity (>1.2)	False negative
	High pH (>8.5)	False negative
	Ascorbic acid (> 40 mg/dL)	False negative
	Elevated ketones (>40 mg/dL)	False negative
Bilirubin	Selenium	False positive
	Pyrindum (drug metabolite)	False positive
	Indoxyl sulfate	Test inoperative – unable to read
	Therapeutic dyes	False positive
Ketones	Colored contaminates	False positive
	L-dopa and metabolites	False positive
	High specific gravity (>1.025)	False positive
	Low pH	False positive
	Phenosulfonphthalein(>0.05 mg/dL)	False positive
Blood (hemolyzed and non-hemolyzed)	Microbial peroxidase	False positive
	Ascorbic acid (>40 mg/dL)	False negative
Specific Gravity	Elevated proteins (>300 mg/dL	High specific gravity not indicative of high urine electrolytes
	Buffered alkaline samples (pH > 8.5)	Low reported specific gravity
	Buffered acidic samples (pH < 5)	Low reported specific gravity
pH	Cross-contamination from adjacent reagent pads	Low reported pH
Protein	Turbidity/ Lipemic samples	Test inoperative – unable to read
	High pH (>9)	False positive
Nitrite		
	Ascorbic acid	False negative
Leukocyte	High glucose (>1000 mg/dL)	Low reported WBC/µL
	High albumin (>1000 mg/dL)	Low reported WBC/µL
	Formaldehyde (>5%)	Low reported WBC/µL
	Oxalic acid (>50 mg/dL)	Low reported WBC/µL
	Oxidizing agents (permanganate)	Low reported WBC/µL

f. Assay cut-off:

Not applicable for devices of this type. The performance of the device around

the "not present"/"present" cutoff is discussed under d) Detection Limit above.

2. Comparison studies:

a. Method comparison with predicate device:

The company conducted a method comparison of the submitted device to the legally marketed predicate, the Bayer Multistix 10 SG. Using fresh negative and spiked urine samples, 3 pathologists recorded the results of measurements on 300 samples made with the proposed device and to those made with the Bayer predicate. Strips from 3 manufacturing lots of the propose device were used in the comparison. Measurements were made according to the respective product inserts.

For the specific gravity, the company the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device	**1.030**	0	0	0	0	0	0	50
	1.025	0	0	0	0	10	54	18
	1.020	0	0	0	8	56	0	0
	1.015	0	0	15	48	1	0	0
	1.010	0	0	33	1	0	0	0
	1.005	0	6	0	0	0	0	0
	1.000	0	0	0	0	0	0	0
	SG	**1.000**	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**
	Predicate Device							

For pH, the company the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device	**9**	0	0	0	0	3	2	7
	8	0	0	0	0	15	8	3
	7	0	0	2	43	3	2	1
	6.5	2	5	21	12	0	0	0
	6	12	84	17	2	0	0	0
	5	47	9	0	0	0	0	0
	pH	**5**	**6**	**6.5**	**7**	**7.5**	**8**	**8.5**
	Predicate Device							

For urobilinogen, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device (mg/dL)						
	8	0	0	0	3	55
	4	0	0	3	53	4
	2	0	3	54	3	1
	1	0	53	3	1	0
	0.1	60	4	0	0	0
	Uro	**0.1**	**1**	**2**	**4**	**8**
	Predicate Device (mg/dL)					

For glucose, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device (mg/dL)							
	>1000	0	0	1	3	33	19
	500	0	0	3	54	5	1
	250	0	4	53	2	2	0
	100	0	54	3	1	0	0
	Negative	60	2	0	0	0	0
	Glucose	**Negative**	**100**	**250**	**500**	**1000**	**2000**
	Predicate Device (mg/dL)						

For urinary bilirubin, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device					
	3+	0	2	2	72
	2+	0	4	71	3
	1+	4	70	5	5
	Negative	56	4	2	0
	Bilirubin	**Negative**	**1+**	**2+**	**3+**
	Predicate Device				

For urinary ketones, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device (mg/dL)							
	>100	0	0	1	3	34	18
	40	0	0	2	50	4	2
	15	0	4	52	4	2	0
	5	2	51	4	3	0	0
	Negative	58	5	1	0	0	0
	Ketones	**Negative**	**5**	**15**	**40**	**80**	**160**
	Predicate Device (mg/dL)						

For hemolyzed urinary blood, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device (RBC/µl)	**250**	0	0	0	5	43
	50	0	0	5	41	5
	10	4	45	45	4	2
	Negative	56	5	0	0	0
	Hemolyzed Blood	**Negative**	**10**	**25**	**80**	**250**
	Predicate device (RBC/µl)					

For non-hemolyzed blood in the urine, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device (RBC/µl)	**80**	0	1	17
	10	4	17	3
	Negative	56	2	0
	Non-hemolyzed blood	**Negative**	**10**	**80**
	Predicate device (RBC/µl)			

For urinary protein, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device (mg/dL)	**1000**	0	0	0	0	2	18
	300	0	0	0	3	35	2
	100	0	0	1	55	3	0
	30	0	3	54	2	0	0
	15	3	53	4	0	0	0
	Negative	57	4	1	0	0	0
	Protein	**Negative**	**15**	**30**	**100**	**300**	**1000**
	Predicate device (mg/dL)						

For nitrite, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device	**Positive**	0	11	95
	+/-	0	87	5
	Negative	100	2	0
	Nitrite	**Negative**	**+/-**	**Positive**
	Predicate device			

For leukocytes in the urine, the company demonstrated the following correlation between the proposed and predicate device:

Proposed Device (Leu/µL)	**500**	0	0	3	4	55
	75	0	3	54	54	3
	25	2	44	2	2	2
	Negative	58	13	1	0	0
	Leukocytes	**Negative**	**15**	**70**	**125**	**500**
	Predicate device (Leu/µL)					

b. Matrix comparison:

The CYBOW 11 Reagent Strips for Urinalysis are only for use with urine.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable for a device of this type.

b. Clinical specificity:

Not applicable for a device of this type.

c. Other clinical supportive data (when a. and b. are not applicable):

The company demonstrated the equivalence of their proposed device to their predicate using patient samples analyzed in the environment in which the device will be used. The company undertook a clinical comparison of the device to the predicate at 2 hospitals' clinical laboratories. A total of 909 patient samples were compared over 30 days.

The clinical comparison followed CLSI EP9A "Method Comparison and Bias Estimation Using Patient Samples". In the study, the company used 3 different manufacturing lots for the proposed device and 3 different lots of strips from the cleared, on-market predicate.

Fresh urine samples obtained during routine processing at the medical facility were analyzed within 4 hours of collection. The fresh urine samples were detergent-free and were not centrifuged or spiked. Strip readings were conducted by laboratory personnel according to the respective device instructions.

For urobilinogen, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device (mg/dL)	**8**	0	0	0	3	6
	4	4	0	2	16	5
	2	9	6	17	4	2
	1	10	22	6	1	0
	Normal	771	24	1	0	0
	Urobilinogen	**Normal**	**1**	**2**	**4**	**8**
	Predicate Device (mg/dL)					

For glucose, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device (mg/dL)	**1000**	0	0	2	6	36	34
	500	0	1	15	40	2	3
	250	1	14	59	6	0	0
	100	23	53	7	5	0	0
	Negative	575	24	3	0	0	0
	Glucose	**Negative**	**100**	**250**	**500**	**1000**	**2000**
	Predicate Device (mg/dL)						

For bilirubin, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device (mg/dL)	**3+**	0	1	4	21
	2+	0	4	24	3
	1+	30	29	10	7
	Negative	750	21	5	0
	Bilirubin	**Negative**	**1+**	**2+**	**3+**
	Predicate Device (mg/dL)				

For urinary ketones, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device (mg/dL)	**>100**	0	0	0	3	33	0
	40	0	0	4	47	9	0
	15	7	8	32	10	4	0
	5	17	45	8	2	0	0
	Negative	658	20	2	0	0	0
	Ketones	**Negative**	**5**	**15**	**40**	**80**	**160**
	Predicate Device (mg/dL)						

For specific gravity, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device	**1.030**	0	0	0	0	11	33	62
	1.025	0	0	0	16	37	63	13
	1.020	0	0	20	62	91	30	9
	1.015	0	11	49	102	42	3	0
	1.010	4	58	83	9	2	0	0
	1.005	6	56	16	4	0	0	0
	1.000	14	4	0	0	0	0	0
	SG	**1.000**	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**
	Predicate Device							

For urinary blood, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device (RBC/µl)	**250**	0	0	7	18	128
	50	3	22	28	120	20
	10	12	98	101	26	8
	Negative	280	28	9	1	0
	Hemolyzed Blood	**Negative**	**10**	**25**	**80**	**250**
	Predicate device (RBC/µl)					

For urinary pH, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device	**9**	0	0	0	0	0	0	9
	8	0	0	0	12	21	67	10
	7	0	2	15	110	92	16	0
	6.5	5	21	75	32	7	2	0
	6	61	159	37	7	1	0	0
	5	92	50	6	0	0	0	0
	pH	**5**	**6**	**6.5**	**7**	**7.5**	**8**	**8.5**
	Predicate Device							

For urinary protein, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device (mg/dL)	**4+**	0	0	0	0	2	18
	3+	0	0	0	3	35	2
	2+	0	0	1	55	3	0
	1+	0	3	54	2	0	0
	+/-	3	53	4	0	0	0
	Negative	57	4	1	0	0	0
	Protein	**Negative**	**+/-**	**1+**	**2+**	**3+**	**4+**
	Predicate device (mg/dL)						

For urinary nitrite, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device	**Positive**	6	4	108
	+/-	10	43	8
	Negative	711	10	9
	Nitrite	**Negative**	**+/-**	**Positive**
	Predicate device			

For urinary leukocytes, the company demonstrated the following correlation between the proposed and predicate device using patient samples in a clinical lab setting:

Proposed Device (Leu/µL)	**500**	1	0	2	10	100
	75	9	6	95	79	20
	25	3	66	21	24	5
	Negative	378	79	10	0	0
	Leukocytes	**Negative**	**15**	**70**	**125**	**500**
	Predicate device (Leu/µL)					

4. Clinical cut-off**:**

   Not applicable for a device of this type.

5. Expected values/Reference range:

   The company indicated the following published[1] reference ranges for their analytes:

   Urobilinogen: 0.1 to 1.0 Ehrlich unit /dL
   Glucose: < 100 mg/dL
   Bilirubin: < Trace
   Ketones: 0 mg/dL in urine with this test
   pH: 5 - 9.
   Blood: < 3 RBC/µL
   Specific Gravity (SG): 1.001 to 1.035.
   Protein: <20mg/dL.
   Nitrite: 0 mg/dL
   Leukocyte: Negative
   Ascorbic acid: urinary output of 20-30 mg/day

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

[1] Kaplan L.A. and Pesce A.J., Clinical Chemistry Theory, Analysis and Correlation, C.V. Mosby. pp. 1004-1007 (1984).